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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,340	10/25/1999	THOMAS SANDAL	5600.200-US	1759

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/18/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,340

Applicant(s)

SANDAL ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 19.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to paper no. 21, filed August 20, 2002. Claims 1 and 21 have been amended, and claims 1-19, 21-25, and 27 are now pending. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

3. Claims 1-19, 21-25, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19, 21-25, and 27 are indefinite over the recitation of the phrase "said enriched pool of organisms is prepared without screening the organisms for presence of the activity of interest" in claims 1 and 21. First, there is insufficient antecedent basis for the limitation "said enriched pool of organisms." Second, it is unclear as to whether the recitation of "the organisms" in this phrase is intended to refer back to organisms in the "environmental pool of organisms" or to organisms in "said enriched pool of organisms." Third, as the claims are clearly intended to encompass "cultivation under conditions"

that have the effect of accomplishing "screening" (see the conditions recited in dependent claims 2 and 3, and the discussion in paragraph 4, below), it is unclear as to how this recitation is intended to further limit the claimed methods. Clarification is required.

Claim Rejections - 35 USC § 103

4. Claims 1-7, 13-19, 21-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duvick et al (WO 96/06175 [2/1996]) in view of Sarkar and Upadhyay (Folia Microbiologica 38(1):29-32 [1993]), for the reasons set forth below and in the Office action of paper no. 18.

The response traverses the rejection on the following grounds. The response states that "An advantage of the present invention is that the gene library can be prepared without the need to first carryout strain selection and screening (i.e., phenotype checks) to identify or purify suitable DNA sources," and that the amended claims "further clarify this aspect of the present invention by reciting that the process entails preparing a gene library from the enriched environmental pool of organisms wherein both the enriched pool or [sic] organisms and the gene library are prepared 'without screening the organisms for presence of the activity of interest.'" The response argues that "Duvick et al. is entirely remove [sic] from the claimed invention as Duvick et al. discloses a process which requires strain selection and screening to identify organisms possessing the activity of interest before the gene library is prepared," and urges that Duvick et al does in fact disclose a screening process, as "a genomic library from microorganism is prepared only after first selecting and screening the sample to

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identify the activity of interest," referring to p. 24, lines 19-20. The response further argues that the Sarkar and Upadhyay reference "does not cure the defects of Duvick et al," and that "the instant invention does not either go through the preliminary screening process taught by Duvick et al. or start through the isolation of a specific organism."

Applicants' arguments have been thoroughly considered but are not persuasive. While Applicants have amended the claims such that step a) recites the limitation "wherein said enriched pool of organisms is prepared without screening the organisms for presence of the activity of interest," the claims as written encompass methods in which the cultivation conditions of step a) include "culturing in a medium that contains a substrate for the gene product encoded by said DNA" and wherein "the substrate constitutes the carbon source and/or nitrogen source of the medium" (see, e.g., dependent claims 2 and 3). Thus, the claims clearly encompass methods in which the growth conditions employed have the effect of "screening," as organisms growing under the conditions employed in the method are organisms capable of growth on or in the selected growth medium. The steps disclosed by Duvick et al of, e.g., growing seed and stalk samples in medium containing fumonisin as the sole carbon source, are in fact equivalent to the steps of applicants' invention as recited in dependent claims 2 and 3. The fact that Duvick et al refers to a step of growth in medium containing a carbon-source substrate as a type of screening (see, e.g., p. 18 of Duvick et al), whereas Applicants do not, does not result in any material difference in the steps themselves. Further, the use of the open transitional language "comprising" allows for the inclusion of additional steps, including "screening," as steps separate from those in the claims

that specifically exclude "screening." Regarding the recitation at page 24, lines 19-20 of Duvick et al, it is noted that the growth conditions employed by Duvick et al – which are equivalent to those encompassed by the claims, as discussed immediately above – result in a population of organisms "demonstrating fumonisin-resistance." This recitation in Duvick et al does not indicate the need for any further steps of screening, for the use of "isolated" microorganisms, etc., and the reference does not suggest that any further processing, screening, or selection of "microorganisms demonstrating fumonisin-resistance" is necessary prior to preparation of a genomic library. Rather, at pages 24-25, Duvick et al disclose additional steps that may occur after library preparation; such additional steps are clearly encompassed by the claims due to the recitation of open transitional language therein. Thus, the steps of Duvick et al's methods correspond to those claimed by applicants. Regarding the Sarkar and Upadhyay reference, it is noted that this reference was not cited to "cure the defects of Duvick et al.," but rather for its teaching of particular environmental pools of organisms, specific growth conditions, and nucleic acids encoding particular types of polypeptides, as set forth in the Office action of paper no. 18. Accordingly, Applicants' arguments are not persuasive.

The combined references of Duvick and Sarkar and Upadhyay suggest all the limitations of present claims 1-7, 13-19, 21-25 and 27, and therefore this rejection is maintained.

5. Claims 1-9, 13-19, 21-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duvick et al in view of Cotta (Appl. Environment. Microbiol.

54(3):772-776 [3/1988]), for the reasons set forth below and in the Office action of paper no. 18.

First, the response traverses the rejection for the same reasons set forth in paragraph 4, above. Accordingly, the response to those arguments applies equally herein. Second, the response argues that "Cotta fails to cure the defects of Duvick et al" because "Knowledge that there are several bacteria in the presence of the rumen of cattle does not teach or suggest to an artisan a process for preparing a gene library from the enriched environmental pool of organisms without first screening the organisms for presence of the activity of interest." This argument has been thoroughly considered but is not found persuasive. The Cotta reference was not cited for a teaching of a process of gene library preparation, but rather for its teaching that the rumen of cattle contain bacteria producing amylases that degrade starch (see page 9 of paper no. 18). The steps of gene library preparation cited in applicants' argument are disclosed in the Duvick et al reference, as was clearly set forth on pages 8-9 of paper no. 18, with the Cotta reference being cited merely for its teaching of a type of environmental pool and a particular type of polypeptide. Accordingly, applicants' argument is not persuasive.

The combined references of Duvick and Cotta suggest all the limitations of present claims 1-9, 13-19, 21-25, and 27, and therefore this rejection is maintained.

6. Claims 1- 8, 10, 12-19, 21-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duvick et al in view of Jacobsen and Schlein (J. Euk. Microbiol.

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44(3):216-219 [1997]), for the reasons set forth below and in the Office action of paper no. 18.

First, the response traverses the rejection for the same reasons set forth in paragraph 4, above. Accordingly, the response to those arguments applies equally herein. Second, the response argues that Jacobsen et al "fails to cure the defects of Duvick et al" because "Knowledge that '*Leishmania* present in the midgut of the sandfly *phlebotomus paptasi* produce cellulases' does not teach or suggest to an artisan a process for preparing a gene library from the enriched environmental pool of organisms without first screening the organisms for presence of the activity of interest." This argument has been thoroughly considered but is not found persuasive. The Jacobsen et al reference was not cited for a teaching of a process of gene library preparation, but rather for its teaching of a type of environmental pool and a particular type of polypeptide, and its teaching of a step of feeding a particular enzyme substrate (see pages 11-12 of paper no. 18). The steps of gene library preparation cited in applicants' argument are disclosed in the Duvick et al reference, as was clearly set forth on pages 10-11 of paper no. 18. Accordingly, applicants' argument is not persuasive.

The combined references of Duvick and Jacobsen and Schlein suggest all the limitations of present claims 1-8, 10, 12-19, 21-25, and 27, and therefore this rejection is maintained.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duvick et al in view of Jacobsen and Schlein, as applied to claims 1- 8, 10, 12-19, 21-25, and

27, above, and further in view of Siegle et al (US Patent No.4,027,037), for the reasons set forth below and in the Office action of paper no. 18.

First, the response traverses the rejection for the same reasons set forth in paragraph 4, above. Accordingly, the response to those arguments applies equally herein. Second, the response argues that "addition of Jacobsen et al. and Siegle et al. fails to cure the defects of Duvick et al" because "Knowledge that '*Leishmania* present in the midgut of the sandfly *phlebotomus paptasi* produce cellulases' of Jacobsen et al. combined with 'a variety of orders and species of arthropods' of Siegle et al does not teach or suggest to an artisan a process for preparing a gene library from the enriched environmental pool of organisms without first screening the organisms for presence of the activity of interest." This argument has been thoroughly considered but is not found persuasive. The Jacobsen et al and Siegle et al references were not cited for a teaching of a process of gene library preparation. Rather, Jacobsen et al was cited for teaching of a type of environmental pool and a particular type of polypeptide, and its teaching of a step of feeding a particular enzyme substrate (see pages 11-12 of paper no. 18), while Siegle et al was cited for disclosing a particular environmental pool or organisms (see page 12 of paper no. 18). The steps of gene library preparation cited in applicants' argument are disclosed in the Duvick et al reference, as was clearly set forth on pages 10-11 of paper no. 18. Accordingly, applicants' argument is not persuasive.

The combined references of Duvick, Jacobsen and Schlein, and Siegle et al suggest all the limitations of present claim 11, and therefore this rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
November 12, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600